1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

FOLON TABLETS (Folic Acid Tablets BP 5 mg)

2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Folic Acid BP 5 mg

3. Pharmaceutical form:

Yellow coloured, circular, flat uncoated tablets having a break line on one side of each tablet and other side is plain.

4. Clinical particulars:

4.1 Therapeutic Indications:

Folic acid is indicated for the treatment of megaloblastic anaemia due to folic acid deficiency. It is also used for prophylaxis in chronic haemolytic states, in renal dialysis, and in drug induced folate deficiency.

Folic acid is used for the prevention of recurrence of neural tube defects.

4.2 Posology and Method of Administration:

Adults

In folate deficient megaloblastic anaemia:

5mg daily for 4 months

Up to 15mg daily may be necessary for malabsorption states

For prophylaxis in chronic haemolytic states or in renal dialysis:

5mg every 1-7 days depending on diet and underlying disease.

In drug induced folate deficiency:

5mg daily

Prevention of recurrence of neural tube defects

5mg daily starting before conception and continuing throughout the first trimester of pregnancy is recommended.

Paediatric population

Over 1 year : As adult dose

Up to 1 year: 500µg/kg daily

Method of Administration: Oral.

4.3 Contraindications:

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients with malignant disease, unless megaloblastic anaemia due to folic acid deficiency.

4.4 Special warnings and precautions for use:

Folic acid should not be administered for treatment of pernicious anaemia or undiagnosed megaloblastic anaemia without sufficient amounts of cyanocobalamin (vitamin B_{12}) as folic acid alone will not prevent and may precipitate development of subacute combined degeneration of the spinal cord. Therefore a full clinical diagnosis should be made before initiating treatment.

Folate should not be routinely used in patients receiving coronary stents.

Caution should be exercised when administering folic acid to patients who may have folate dependent tumours.

Folic acid is removed by haemodialysis.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interaction:

Absorption of folic acid may be reduced by sulfasalazine.

Concurrent administration with cholestyramine may interfere with folic acid absorption. Patients on prolonged cholestyramine therapy should take folic acid 1 hour before or 4 to 6 hours after receiving cholestyramine.

Antibiotics may interfere with the microbiological assay for serum and erythrocyte folic acid concentrations and may cause falsely low results.

Trimethoprim or sulfonamides, alone or in combination as co-trimoxazole, may reduce the effect of folic acid and this may be serious in patients with megaloblastic anaemia.

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

Serum levels of anticonvulsant drugs (phenytoin, phenobarbital, primidone) may be reduced by administration of folate and therefore patients should be carefully monitored by the physician and the anticonvulsant drug dose adjusted as necessary.

Fluorouracil toxicity may occur in patients taking folic acid and this combination should be avoided.

Edible clay or antacids containing aluminium or magnesium may reduce folic acid absorption. Patients should be advised to take antacids at least two hours after administration of folic acid.

Folic acid may reduce intestinal absorption of zinc (of particular importance in pregnancy).

4.6 Fertility, pregnancy and lactation

Pregnancy

Folic acid deficiency during pregnancy may lead to the appearance of foetal malformations. Imbalance in folate requiring trophoblast cells may also lead to detachment of the placenta.

Very high doses of folic acid have been shown to cause foetal abnormalities in rats; however, harmful effects in the human foetus, mother or the pregnancy have not been reported following ingestion of folic acid.

Breastfeeding

Folic acid is excreted in breast milk.

No adverse effects have been observed in breast-fed infants whose mothers were receiving folic acid.

4.7 Effects on ability to drive and use machines:

None known

4.8 Undesirable effects:

Folic acid is generally well tolerated although the following side effects have been reported:

Blood and lymphatic system disorders:

Folic acid may worsen the symptoms of co-existing vitamin B_{12} deficiency and should never be used to treat anaemia without a full investigation of the cause.

Immune system disorders:

Rare: Allergic reactions, comprising erythema, rash, pruritus, urticarial, dyspnoea, and anaphylactic reactions (including shock).

Gastrointestinal disorder:

Abdominal distension, flatulence, anorexia and nausea.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

4.9 Overdose:

No cases of acute overdosage appear to have been reported, but even extremely high doses are unlikely to cause harm to patients. No special procedures or antidote are likely to be needed.

5. Pharmacological properties:

5.1 Pharmacokinetic Properties:

The mucosa of the duodenum and upper part of the jejunum are rich in dihydrofolate reductase, where folates and folic acid are absorbed. Once absorbed, folic acid is rapidly reduced and then methylated to form tetrahydrofolic acid derivatives which are rapidly transported to the tissues.

5.2 Pharmacodynemic Properties:

Folic acid is readily absorbed following oral dosage, and is extensively bound to plasma proteins.

Folic acid is absorbed rapidly from the small intestine, primarily from the proximal portion. Naturally occurring conjugated folates are reduced enzymatically to folic acid in the gastrointestinal tract prior to absorption. Folic acid appears in the plasma approximately 15 to 30 minutes after an oral dose; peak levels are generally reached within 1 hour

5.3 Preclinical safety data

Toxicity studies in animals (rats and rabbits) have shown that massive doses (100mg/kg upwards) produce precipitation of folate crystals in renal tubules, particularly proximal tubules and ascending limb of the loop of Henle. Tubular necrosis is followed by recovery.

6. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP
Maize starch	BP
Aspartame	BP
Microcrystalline cellulose powder	BP
Methyl paraben sodium	BP
Propyl paraben sodium	BP
Magnesium stearate	BP
Colloidal silicon dioxide	BP
Polyplasdone XL-10 (Cross Povidone)	USP
Essence orange powder	INH
Sodium Saccharin	BP
Talcum	BP

6.2 Incompatibilities:
None Reported

6.3 Shelf-Life:
36 months from the date of manufacture.

6.4 Special Precautions for Storage:
Do not store above 30°C. Protect from light.

6.5 Nature and Contents of Container:
10 tablets packed in one strip. Such 10 strip packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

6.6 Special precautions for disposal:
No special requirements.

7. Marketing Authorisation Holder and manufacturing Site Addresses:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

8. Marketing Authorisation Number: Rwanda FDA-HMP-MA-1320

9. Date of revision of the text: June 2024

AGOG PHARMA LTD. VASAI

Date:
Director of the manufacturer
(Signature, Full name, Stamp)

AGOG PHARMA LTD. VASAI

Date:
Director of applicant company
(Signature, Full name, Stamp)